INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) Application Number 10596828 Filing Date 2006-06-26 First Named Inventor Tsutomu Ishihara Art Unit 1615 Examiner Name to be assigned Attorney Docket Number KPO-LTT-P5/LTT-98/US

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| Examiner Initial* | Cite No | Patent Number | Kind Code ¹ | Issue D | Issue Date Name of Patentee of Applicant | | | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | | | |
| | 1 | 5091188 | | 1992-02-25 Duncan Haynes | | | | | | | |
| | 2 | 6087324 | | 2000-07-11 Yasutaka Igari | | | | | | | |
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| | 1 | 20040081688 | | 2004-04 | | | | | | | |
| | 2 | 20040185113 | | 2004-09 | | | | | | | |
| If you wis | h to a | ⊥ dd additional U.S. Publi | ⊥ shed Ap | plication | n citation | լ ո information բ | please click the Ado | d button. | Add | | |
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| Examiner Initial* | Cite No | Foreign Document Number ³ | Country Code ² | | Kind Code ⁴ | Publication Date | Name of Patente Applicant of cited Document | e or v | here Rel | or Relevant | T5 |
| | 1 | 2003-081865 | JP | | | 2003-03-19 | Kimura Michio | | | | |
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| Attorney Docket Number | | KPO-LTT-P5/LTT-98/US | | |

| | 2 | WO 99/43426 | wo | | 1999-09-02 | Philippe Grisoni | | | |
|---|------------|---|----------------|----------|----------------|---------------------------|--------|--|--|
| | 3 | EP 1 342471 B1 | EP | | 2003-04-02 | Jean-Thierry Simonnet | | | |
| | 4 | WO 00/67800 | wo | | 2000-11-16 | Rainer Muller | | | |
| If you wis | h to ac | dd additional Foreign Pa | atent Document | citation | information pl | ease click the Add buttor | 1 Add | | |
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| | 1 | MITSUKO TAKENAGA, "A novel sustained-release formulation of insulin with dramatic reduction in initial rapid release", Journal of Controlled Release, vol. 79, p. 81-91 (2002), Elsevier, Japan | | | | | | | |
| | 2 | "Clinical Pharmacology", Jpn. J. Clin. Pharmacol. Ther., vol. 26(1), p. 127-128 (1995), Japan | | | | | | | |
| | 3 | "DRUG DELIVERY SYSTEM Today's DDS drug delivery system", Iyaku Medicine and Drug Journal, p. 325-331 (1999), Japan | | | | | | | |
| | 4 | SADASUKE OKANO, "Shin Yakuzaigaku Soron", New General Statement of Pharmaceutics, Revision 3, p. 65-66 (April 10, 1987), Nankodo Co., Japan | | | | | | | |
| | 5 | YOKO YAMAGUCHI, et al., "All-trans Retinoic Acid (ATRA) - CaCO3 Nano-particle no Johosei no Kento", Lecture Summary of Seventeenth Annual Meeting of Academy of Pharmaceutical Science and Technology, p. 88, (March 27, 2002), Japan | | | | | | | |
| | 6 | AKIRA YAMAMOTO, "Improvement of Transmucosal Absorption of Biologically Active Peptide Drugs", Yakugaku Zasshi, vol. 121, p. 929-948 (2001) Japan. | | | | | | | |
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| Sigr | nature | /manette dennis/ | Date (YYYY-MM-DD) | 2007-02-16 | | | | | |
| Nan | ne/Print | Manette Dennis | Registration Number | 30,623 | | | | | |
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